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EXAMINER	
HARLE, JENNIFER I	

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3627	

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/942,803	Applicant(s) MCQUADE ET AL.	
	Examiner Jennifer I. Harle	Art Unit 3627	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 August 2001*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-9* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-9* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Claims 1-9 are pending. Claims 1-9 are rejected.

Lexicography

After careful review of the specification and prosecution history, the Examiner is unaware of any desire—either expressly or implicitly—by Applicant(s) to be their own lexicographer and to define a claim term to have a meaning other than its ordinary and accustom meaning. Therefore, the Examiner starts with the presumption that all claim limitations are given their ordinary and accustom meaning. See *Bell Atlantic Network Services Inc. v. Covad Communications Group Inc.*, 262 F.3d 1258, 1268, 59 USPQ2d 1865, 1870 (Fed. Cir. 2001)("[T]here is a heavy presumption in favor of the ordinary meaning of claim language as understood by one of ordinary skill in the art."); *CCS Fitness Inc. v. Brunswick Corp.*, 288 F.3d 1359,1366, 62 USPQ2d 1658, 1662 (Fed. Cir. 2002) (There is a "heavy presumption that a claim term carries its ordinary and customary meaning."). See also MPEP §2111.01 and *In re Zletz*, 893 F.2d 319, 321, 13 USPQ2d 1320, 1322 (Fed. Cir. 1989).[1]

In accordance with the ordinary and accustom meaning presumption, during examination the claims are interpreted with their "broadest reasonable interpretation . . . ." *In re Morris*, 127 F.3d 1048, 1054, 44 USPQ2d 1023, 1027 (Fed. Cir. 1997).[2]

However, if Applicant(s) wish to use lexicography and desire a claim limitation to have a meaning other than its ordinary and accustom meaning, the Examiner respectfully requests

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[1] It is the Examiner's position that "plain meaning" and "ordinary and accustom meaning" are synonymous. See e.g. *Rexnord Corp. v. Laitram Corp.*, 274 F.3d 1336, 1342, 60 USPQ2d 1851, 1854 (Fed. Cir. 2001) ("[A]ll terms in a patent claim are to be given their plain, ordinary and accustomed meaning . . .").

[2] See also MPEP §2111; *In re Graves*, 69 F.3d 1147, 1152, 36 USPQ2d 1697, 1701 (Fed. Cir. 1995); *In re Etter*, 756 F.2d 852, 858, 225 USPQ 1, 5 (Fed. Cir. 1985) (en banc).

Applicant(s) in their next response to expressly indicate[3] the claim limitation at issue[4] and to show where in the specification or prosecution history the limitation is defined. Such definitions must be clearly stated in the specification or file history. *Bell Atlantic*, 262 F.3d at 1268, 59 USPQ2d at 1870, ("[I]n redefining the meaning of particular claim terms away from the ordinary meaning, the intrinsic evidence must 'clearly set forth' or 'clearly redefine' a claim term so as to put one reasonably skilled in the art on notice that the patentee intended to so redefine the claim term").[5] The Examiner cautions that no new matter is allowed.

Failure by Applicant(s) in their next response to address this issue or to be non-responsive to this issue entirely will be considered a desire by Applicant(s) to forgo lexicography in this application and to continue having the claims interpreted with their ordinary and accustom meaning and with their broadest reasonable interpretation. Additionally, it is the Examiner's position that above requirements are reasonable.[6] Applicant(s) are also cautioned that even

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[3] "Absent an *express intent* to impart a novel meaning, terms in a claim are to be given their ordinary and accustomed meaning. [Emphasis added.]" *Wenger Manufacturing Inc. v. Coating Mach. Sys.*, Inc., 239 F.3d 1225, 1232, 57 USPQ2d 1679, 1684 (Fed. Cir. 2001) (citations and quotations omitted). "In the absence of an *express intent* to impart a novel meaning to claim terms, an inventor's claim terms take on their ordinary meaning. We indulge a heavy presumption that a claim term carries its ordinary and customary meaning. [Emphasis added.]" *Teleflex Inc. v. Ficosa North America Corp.*, 299 F.3d 1313, 1325, 63 USPQ2d 1374, 1380 (Fed. Cir. 2002) (citations and quotations omitted).

[4] "In order to overcome this heavy presumption in favor of the ordinary meaning of claim language, it is clear that a party wishing to use statements in the written description to confine or otherwise affect a patent's scope must, at the very least, point to a term or terms in the claim with which to draw in those statements." *Johnson Worldwide Assocs. v. Zebco Corp.*, 175 F.3d 985, 989, 50 USPQ2d 1607, 1610 (Fed. Cir. 1999).

[5] See also *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1582, 39 USPQ2d 1573, 1576 (Fed. Cir. 1996), ("[A] patentee may choose to be his own lexicographer and use terms in a manner other than their ordinary meaning, *as long as* the special definition of the term is *clearly stated* in the patent specification or file history. [Emphasis added.]"); *Multiform Desiccants Inc. v. Medzam Ltd.*, 133 F.3d 1473, 1477, 45 USPQ2d 1429, 1432 (Fed. Cir. 1998) ("Such special meaning, however, must be sufficiently clear in the specification that any departure from common usage would be so understood by a person of experience in the field of the invention.").
See also MPEP §2111.02, subsection titled "Applicant May Be Own Lexicographer" and MPEP §2173.05(a) titled "New Terminology."

[6] The requirements are reasonable on at least two separate and independent grounds: first, the Examiner's requirements are simply an express request for clarification of how Applicant(s) intend their claims to be interpreted. Second, the requirements are reasonable in view of the USPTO's goals of compact prosecution, productivity with

though claim interpretation begins with this presumption, after issuance the prosecution history may further limit claim scope if Applicant(s) disclaim or disavow a particular interpretation of the claims during prosecution. *Abbott Laboratories v. TorPharm Inc.*, 300 F.3d 1367, 1372, 63 USPQ2d 1929, 1931 (Fed. Cir. 2002). Unless expressly noted otherwise by the Examiner, the preceding claim interpretation principles apply to all examined claims currently pending.

Applicant has failed to define the terms propriety or proprietor in the specification or drawings. The examiner does note drawing 4, which shows a validation process but the discussion in the specification does not require all this information but merely that required under current regulations. Specification, pg. 16, lines 12-14. Thus, the examiner offers the following standard dictionary definitions for those terms:

Propriety: property, quality of a person or thing. Merriam Webster's Collegiate Dictionary, Tenth Edition, 1996, pg. 936. Taken in this context the examiner interprets the meaning of propriety to encompass as little as whether the request has met the basic requirement for distribution, i.e. the requirements under the PDMA.

Proprietor: one who has the legal right or exclusive title to something: owner. Id.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 4 and 6 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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particular emphasis on reductions in both pendency and cycle time, and other goals as outlined in the USPTO's The

Claims 4 and 6 recite the limitation "the central inventory's proprietor" in line 2. There is insufficient antecedent basis for this limitation in the claim. There is no teaching for this limitation in the specification or the drawings. It is unclear whether this is an individual or a computer module or a combination of the two. Additionally, the specification and drawings fail to teach what is encompassed in propriety.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over the product SampleTrak™ incorporating PhasTrak™ as primarily taught in BusinessWire, IMS Health Strategic Technologies Launches SampleTrak, the First Web-Based Solution for Managing prescription Drug Sampling, April 19, 2000, pg. 1 (supporting references are utilized to illustrate the features in the footnotes).

As per claim 1, BusinessWire teaches a method for tracking the distribution of controlled articles from a central inventory by means of electronic communication and data collection, comprising:

a) receiving in a system server, a distribution request from a remote distributing representative for distribution of a packet of articles to a distributee (Field representatives are able to order samples and receive shipment acknowledgement via the Web), the request

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21st Century Strategic Plan, June 3, 2002 available at www.uspto.gov/web/offices/com/strat2001/index.htm.

comprising a representative identifier, a distributee identifier (announced the launch of SampleTrak™, a unique, integrated product that provides pharmaceutical companies with a complete solution for meeting prescription Drug Marketing Act Final Rules in the U.S. ... SampleTrak enables pharmaceutical administrators to electronically validate a physicians eligibility to receive samples ... verified signature of a physician receiving a sample)[7], and a statement describing the contents of the packet of articles being distributed from a local

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[7] According to the **PDMA Final Rules Subpart F – Request and Receipt Forms, Reports, and Records § 203.60** (a) *Use of electronic records, electronic signatures, and handwritten signatures executed to electronic records.* (1) Provided the requirements of part 11 of this chapter are met, electronic records, electronic signatures, and handwritten signatures executed on paper may be used as an alternative to paper records and handwritten signatures executed on paper to meet any of the record and signature requirements of PDMA, PDA, or this part. 21 CRF Parts 203 and 205 [docket Nos. 92N-0297 and 88N0258] RIN 0910-AA08, Prescription Drug Marketing Act of 1987; Prescription Drug Amendments of 1992; Policies, Requirements, and Administrative Procedures, Final Rule, 64 FR 677220, 67762, December 3, 1999. §203.31(b) Sample distribution by means other than mail or common carrier (direct delivery by a representative or detailer) Contents of the written request forms for delivery of samples by a representative. (1) A written request for delivery of a drug sample by a representative to a licensed practitioner is required to contain the following: (d) Inventory and reconciliation of drug samples of manufacturers' and distributors' representatives. ... All drug samples in possession or control of each manufacturer's and distributor's representatives are required to be inventoried and the results of the inventory are required to be recorded in an inventory record ... and create a report documenting the reconciliation process ... (1) The inventory record is required to identify all drug samples in a representative's stock ... (2) The reconciliation report is required to include ... (ii) A record of each drug sample shipment received since the most recently completed prior inventory, including the sender and date of the shipment, ... (e) List of manufacturers' and distributors' representatives. Each drug manufacturer and authorized distributor of record who distributes drug samples by means or representatives shall maintain a list of the names and addresses of its representatives who distribute drug samples and of the sites where drug samples are stored. 64 FR 677720,67759-60. 21 CFR Part 11 [Docket No. 92N-0251] RIN 0910-AA29 Electronic Records; Electronic Signatures Part II, Final Rule, 62 CFR 13430, 13465, 13466, March 20, 1997, Subpart A General Provisions, § 11.3 –Definitions. (b)(7) Electronic Signature means a computer data compilation of any symbol or series of symbols executed, adopted or authorized by an individual to be the legally binding equivalent of the individual's handwritten signature. **Subpart B—Electronic Records § 11.10 -- Controls for closed systems.** (a) Validation of systems to ensure accuracy, reliability, consistent intended performance, and the ability to discern invalid or altered records. (d) Limiting system access to authorized individuals. (g)Use of authority check to ensure that only authorized individuals can use the system, electronically sign a record, access the operation or computer system input or output device, alter a record, or perform the operation at hand. (h) Use of device (e.g., terminal) checks to determine, as appropriate, the validity of the source of data input or operational instruction. (j) The establishment of, and adherence to, written policies that hold individuals accountable and responsible for actions initiated under their electronic signatures, in order to deter record and signature falsification. **§ 11.30 – Controls for open systems.** Persons who use open systems to create, modify, maintain, or transmit electronic records shall employ procedures and controls designed to ensure the authenticity, integrity, and, as appropriate, the confidentiality of electronic records from the point of their creation to the point of their receipt. Such procedures and controls shall include those identified in § 11.10, as appropriate, and additional measures ...

Thus, in order to be in compliance with the PDMA in utilizing electronic record keeping, the representative requesting the samples would have to be validated, i.e. authorized to make the request and utilize the system and

inventory associated with the distributing representative (SampleTrak can be seamlessly integrated wit PhasTram™, IMS HEALTH Strategic Technologies' mobile solution for Microsoft Windows CE-based handheld PCs. ... managers can efficiently track and control sample inventories... territory or district sample records can be quickly reproduced for auditing... sample administrators receive advice and guidance on improving the efficiency and control of the sampling process)[8];

b) confirming the authority of the of the distributing representative to distribute the packet (SampleTrak™ , a unique, integrated product that provides pharmaceutical companies with a complete solution for meeting Prescription Drug marketing Act Final Rules in the U.S.)[9];

c) confirming the authority of the distributee to receive the packet (Validation is sent via IMS HEALTH Strategic Technologies' Pharmaceutical Relatiohship Management (PRM) solution directly to filed representatives equipped with laptop or handheld personal computers);

d) confirming the distribution request for propriety (sample administrators receive advice and guidance on improving the efficiency and control of the sampling process);

e) transmitting an authorization code to the distributing representative (Field representatives are able to order samples and receive shipment acknowledgment via the Web and managers can efficiently track and control sample inventories. Additionally, SampleTrak is a

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would require some form of an identifier. Validation of the physicians eligibility requires the system to have a distributee identifier, as does the reconciliation report.

[8] According to the PDMA as set forth above, part of the authorization includes a description of the sample, including the product name dosage, etc.

[9] The PDMA requires that each drug manufacturer or authorized distributor of record who distributes drug samples by means of representatives shall maintain a list of the names and addresses of its representatives who distribute drug samples and of the sites where drug samples are stored. § 203.31(e) 64 FR 67760. Additionally, manufacturers/authorized distributors are required to identify all drug samples in a representative's stock ... Id. (d)(1). Thus, a manufacturer/authorized distributor would have to confirm that the representative was an authorized representative or would be in violation of the PDMA and face the civil and criminal penalties.

unique, integrated product that provides pharmaceutical companies with a complete solution for meeting Prescription Drug Marketing Act Final Rules ...)[10]; and

f) deleting a description of the packet's contents from the local inventory and the central inventory (managers can efficiently track and control sample inventories)[11].

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[10] According to the **PDMA Final Rules Subpart F – Request and Receipt Forms, Reports, and Records § 203.60** (a) *Use of electronic records, electronic signatures, and handwritten signatures executed to electronic records.* (1) Provided the requirements of part 11 of this chapter are met, electronic records, electronic signatures, and handwritten signatures executed on paper may be used as an alternative to paper records and handwritten signatures executed on paper to meet any of the record and signature requirements of PDMA, PDA, or this part. 21 CRF Parts 203 and 205 [docket Nos. 92N-0297 and 88N0258] RIN 0910-AA08, Prescription Drug Marketing Act of 1987; Prescription Drug Amendments of 1992; Policies, Requirements, and Administrative Procedures, Final Rule, 64 FR 677220, 67762, December 3, 1999. §203.31(b) Sample distribution by means other than mail or common carrier (direct delivery by a representative or detailer) Contents of the written request forms for delivery of samples by a representative. (1) A written request for delivery of a drug sample by a representative to a licensed practitioner is required to contain the following: (d) Inventory and reconciliation of drug samples of manufacturers' and distributors' representatives. ... All drug samples in possession or control of each manufacturer's and distributor's representatives are required to be inventoried and the results of the inventory are required to be recorded in an inventory record ... and create a report documenting the reconciliation process ... (1) The inventory record is required to identify all drug samples in a representative's stock ... (2) The reconciliation report is required to include ... (ii) A record of each drug sample shipment received since the most recently completed prior inventory, including the sender and date of the shipment, ... (e) List of manufacturers' and distributors' representatives. Each drug manufacturer and authorized distributor of record who distributes drug samples by means or representatives shall maintain a list of the names and addresses of its representatives who distribute drug samples and of the sites where drug samples are stored. 64 FR 677720,67759-60. 21 CFR Part 11 [Docket No. 92N-0251] RIN 0910-AA29 Electronic Records; Electronic Signatures Part II, Final Rule, 62 CFR 13430, 13465, 13466, March 20, 1997, Subpart A General Provisions, § 11.3 –Definitions. (b)(7) Electronic Signature means a computer data compilation of any symbol or series of symbols executed, adopted or authorized by an individual to be the legally binding equivalent of the individual's handwritten signature. **Subpart B—Electronic Records § 11.10 -- Controls for closed systems.** (a) Validation of systems to ensure accuracy, reliability, consistent intended performance, and the ability to discern invalid or altered records. (d) Limiting system access to authorized individuals. (g)Use of authority check to ensure that only authorized individuals can use the system, electronically sign a record, access the operation or computer system input or output device, alter a record, or perform the operation at hand. (h) Use of device (e.g., terminal) checks to determine, as appropriate, the validity of the source of data input or operational instruction. (j) The establishment of, and adherence to, written policies that hold individuals accountable and responsible for actions initiated under their electronic signatures, in order to deter record and signature falsification. **§ 11.30 – Controls for open systems.** Persons who use open systems to create, modify, maintain, or transmit electronic records shall employ procedures and controls designed to ensure the authenticity, integrity, and, as appropriate, the confidentiality of electronic records from the point of their creation to the point of their receipt. Such procedures and controls shall include those identified in § 11.10, as appropriate, and additional measures ...

Thus, in order to be in compliance with the PDMA in utilizing electronic record keeping, the representative requesting the samples would have to be validated, i.e. authorized to make the request and utilize the system. The transmission of an authorization code is the notification of validation of the request and shipment acknowledgment.

[11] Description of Handheld Solutions Overview teaches that they have integratedInventory into their handheld solutions. See IMS Health Strategic Technologies, Handheld Solutions Overview, http://web.archive.org/web/20000510171451/www.st.imshealth.com/solutions.st_sol)handheld.htm, archived May 10, 2000, printed November 13, 2003. While BusinessWire does not explicitly teach that the inventory deletes a

As per claim 2, BusinessWire teaches that the controlled articles are prescription drug samples (see Title and SampleTrak™ ... the drug sample management solution).

As per claim 3, BusinessWire teaches that the distributing representative is a pharmaceutical company's sale's representative and the distributees are licensed dispensing practitioners (Field representatives are able to order samples and receive shipment acknowledgment via the Web ...SampleTrak enables pharmaceutical sample administrators to electronically validate a physician's eligibility to receive samples ...).

As per claim 4, BusinessWire teaches that the step of evaluating the distribution request for propriety includes applying specific business logic received from the central inventory's proprietor (managers can efficiently track and control sample inventories ... SampleTrak enables pharmaceutical sample administrators to receive advice and guidance on improving the efficiency and control of the sampling process through territory or district sample records auditing, i.e. specific business logic.)

As per claim 5, BusinessWire teaches that the request is received from the remote distributing representative over a communication path including a wireless link (SampleTrak can

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description of the packet's contents from the local inventory and the central inventory, this is how inventory systems operate. Once a product is removed from the area in which it is stored, its description is removed from the current inventory. That is what appears to be occurring in this case. Once the packet is distributed to the distributee, its description is removed from both the central and the local inventory, as it is no longer part of that inventory. See, e.g. Johnson, et al. (5,712,989) Abstract – teaching that each computer has an associated database which can be accessed by that computer and can build and transmit to the other computer communications blocks of data relating to a particular requisition of an item in Just-in-Time inventory or the management of the JIT inventory, col. 36, lines 6-11, the system provides for deletion from the local database when requisition records have been filled; Coffman, et al. (2001/0044731 A1) at Fig. 2 teaches that after current medication /infusion, etc. is delivered to a patient it is archived/moved to storage; Sharood, et al. (2002/0022991 A1) [0193] teaches that the kitchen and laundry assistant centers creates inventories and when an item is used removes it from the inventory; Tilles (2002/0032501 A1) teaches item descriptions are deleted both from the inventory of the item storage carousel and the delivery company as they are removed from each inventory – Fig.1, 10[0031], [0037], [0041], [0043],[0046],[0057], [0059], [0061], Table II – Purge Item, Remove Item; Abreu (2001/0056359 A1) teaches that a product identifier can be removed, i.e. deleted from an inventory/database of product information – Figs. 19A and B, [0304]-[0305].

be seamlessly integrates with PhasTrak™, IMS Health Strategic Technologies' mobile solution for Microsoft Windows CE-based handheld PCs.).[12]

As per Claim 6, BusinessWire teaches the step of transmitting the request and authorization code to the central inventory's proprietor (Field Representatives are able to order samples and receive shipment acknowledgment via the Web, and managers can efficiently track and control sample inventories. Additionally, SampleTrak is a unique, integrated product that provides pharmaceutical companies with a complete solution for meeting Prescription Drug Marketing Act Final Rules ...)[13]

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[12] Description of PhasTrak includes the type of handheld utilized as being available from a number of hardware suppliers including HP, Compaq, Sharp, Casio ...), i.e. including a wireless link. See IMS Health Strategic Technologies, Handheld Solutions Overview, http://web.archive.org/web/20000510171451/www.st.imshealth.com/solutions.st_sol)handheld.htm, archived May 10, 2000, printed November 13, 2003.

[13] According to the **PDMA Final Rules Subpart F – Request and Receipt Forms, Reports, and Records § 203.60** (a) *Use of electronic records, electronic signatures, and handwritten signatures executed to electronic records.* (1) Provided the requirements of part 11 of this chapter are met, electronic records, electronic signatures, and handwritten signatures executed on paper may be used as an alternative to paper records and handwritten signatures executed on paper to meet any of the record and signature requirements of PDMA, PDA, or this part. 21 CRF Parts 203 and 205 [docket Nos. 92N-0297 and 88N0258] RIN 0910-AA08, Prescription Drug Marketing Act of 1987; Prescription Drug Amendments of 1992; Policies, Requirements, and Administrative Procedures, Final Rule, 64 FR 677220, 67762, December 3, 1999. §203.31(b) Sample distribution by means other than mail or common carrier (direct delivery by a representative or detailer) Contents of the written request forms for delivery of samples by a representative. (1) A written request for delivery of a drug sample by a representative to a licensed practitioner is required to contain the following: (d) Inventory and reconciliation of drug samples of manufacturers' and distributors' representatives. ... All drug samples in possession or control of each manufacturer's and distributor's representatives are required to be inventoried and the results of the inventory are required to be recorded in an inventory record ... and create a report documenting the reconciliation process ... (1) The inventory record is required to identify all drug samples in a representative's stock ... (2) The reconciliation report is required to include ... (ii) A record of each drug sample shipment received since the most recently completed prior inventory, including the sender and date of the shipment, ... (e) List of manufacturers' and distributors' representatives. Each drug manufacturer and authorized distributor of record who distributes drug samples by means or representatives shall maintain a list of the names and addresses of its representatives who distribute drug samples and of the sites where drug samples are stored. 64 FR 677720,67759-60. 21 CFR Part 11 [Docket No. 92N-0251] RIN 0910-AA29 Electronic Records; Electronic Signatures Part II, Final Rule, 62 CFR 13430, 13465, 13466, March 20, 1997, Subpart A General Provisions, § 11.3 –Definitions. (b)(7) Electronic Signature means a computer data compilation of any symbol or series of symbols executed, adopted or authorized by an individual to be the legally binding equivalent of the individual's handwritten signature. **Subpart B—Electr nic Rec rds § 11.10 -- Contr ls for closed systems.** (a) Validation of systems to ensure accuracy, reliability, consistent intended performance, and the ability to discern invalid or altered records. (d) Limiting system access to authorized individuals. (g)Use of authority check to ensure that only authorized individuals can use the system, electronically sign a record, access the operation or computer system input or output device, alter a record, or perform the operation at hand. (h) Use of device (e.g.,

As per claim 7, BusinessWire does not specifically teach transmitting a corrective action message to the distributing representative if the evaluation step results in an initial denial of authorization. Customer service is a key factor in the success of any business, whether it is brick and mortar or computerized. The ability to correct mistakes or errors in any system is a crucial factor in customer service. This practice is well known in the business community and would follow in a computerized process for the business community, particularly the pharmaceutical industry where competition is extremely fierce and the use of product samples can play and influential role on the success of a particular drug. Additionally, if a change in authorization is going to occur in the electronic system, the PDMA would require that there be an electronic record, as the sample would have to be requested and signed for under the appropriate rules. Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to have added the well-known step of transmitting a corrective action message to the distributing representative if the evaluation step results in an initial denial of the authorization of BusinessWire for the purpose of increasing customer utilization of the pharmaceutical product upon which the sample is based.

As per claim 8, BusinessWire teaches that the request is received from the remote distributing representative by means of electronic transmission of information entered on a

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terminal) checks to determine, as appropriate, the validity of the source of data input or operational instruction. (j) The establishment of, and adherence to, written policies that hold individuals accountable and responsible for actions initiated under their electronic signatures, in order to deter record and signature falsification. **§ 11.30 – Controls for open systems.** Persons who use open systems to create, modify, maintain, or transmit electronic records shall employ procedures and controls designed to ensure the authenticity, integrity, and, as appropriate, the confidentiality of electronic records from the point of their creation to the point of their receipt. Such procedures and controls shall include those identified in § 11.10, as appropriate, and additional measures ...

Thus, in order to be in compliance with the PDMA in utilizing electronic record keeping, the representative requesting the samples would have to be validated, i.e. authorized to make the request and utilize the system. The transmission of an authorization code is the notification of validation of the request and shipment acknowledgment

sample disbursement form (SampleTrak™ is a unique, integrated product that provides pharmaceutical companies with a complete solution for meeting Prescription Drug marketing Act Final Rules ... SampleTrak can be seamlessly integrated with PhasTrak™, IMS HEALTH Strategic Technologies' mobile solution for Microsoft Windows CE-based handheld PCs. Field representatives are able to order samples ... via the Web...).[14]

As per claim 9, BusinessWire teaches:

a) transmitting the packet from the central inventory to the distributing representative (Field representatives are able to order samples and receive shipment acknowledgment via the Web, and managers can efficiently track and control sample inventories);

b) transmitting an acknowledgement of delivery from the distributing representatives to the system server (managers can efficiently track and control sample inventories ... SampleTrak™ , a unique, integrated product that provides pharmaceutical companies with a complete solution for meeting Prescription Drug Marketing Act Final Rules in the US ...matched to an electronically captured and verified signature of a physician receiving a sample. Territory or district sample records can be quickly reproduced for auditing, and sample administrators receive advice and guidance on improving the efficiency and control of the

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and would have to be stored with the manufacturer as they are required to provide this information in an audit, inventory and reconciliation report.

[14] The core functionality of the handheld devices includes Call/Sample templates, i.e. forms. See IMS Health Strategic Technologies, Handheld Solutions Overview, http://web.archive.org/web/20000510171451/www.st.imshealth.com/solutions.st_sol)handheld.htm, archived May 10, 2000, printed November 13, 2003. Moreover, 21 CRF Parts 203 and 205 [docket Nos. 92N-0297 and 88N0258] RIN 0910-AA08, Prescription Drug Marketing Act of 1987; Prescription Drug Amendments of 1992; Policies, Requirements, and Administrative Procedures, Final Rule, 64 FR 67720, 67759-60, December 3, 1999. § 203.31 -- Sample distribution by means other than mail or common carrier (direct delivery by a representative of detailer). Requires a written request for the sample, which contains specific information that is standardized and signed by the practitioner requesting the sample. Subsection (b) specifically refers to written request **forms** for delivery of samples by a representative. **§ 203.33 – Drug sample forms.** Teaches the methods of delivery for a sample request or receipt form including private courier or electronically or by any other system that the method for transmission

sampling process... sales forces can additionally leverage the portability of handheld PCs and information delivery via the Internet)[15];

c) in the system server, electronically transferring the description of the packet's contents from the central inventory to the local inventory (SampleTrak can be seamlessly integrated with PhasTrak™ ... developed SampleTrak to make accurate sampling compliance faster and easier for pharmaceutical field personel, helping them to be more efficient and productive. Integrated with PhasTrak, sales forces can additionally leverage the portability of handheld PCs and information delivery via the Internet. ... SampleTrak's modular Web-based design enables integration with any sales force automation system ... SampleTrak™, a unique, integrated product that provides pharmaceutical companies with a complete solution for meeting prescription Drug Marketing Act Final Rules).[16]

Conclusion

In accordance with the USPTO's goals of customer service, compact prosecution, and reduction of cycle time, and because "the continual, chief complaint of inventors and their

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meets the security requirements set forth in § 203.60(c). Thus, the use of forms in request sample disbursement is specifically taught in the PDMA final rules and in the reference.

[15] Under the PDMA the manufacturer and/or authorized distributor is responsible for maintaining records for inventory purposes that detail the name and address of each recipient of each sample unit shipped, the date of the shipment, and the proprietary or established name, dosage strength, and number of sample units shipped ...§ 203.31(d). Thus, in an electronic system there would have to be some form of acknowledgement of delivery from the distributing representatives to the system server.

[16] To be PDMA compliant, the electronic record in the PDA would have to have basic information about the product shipped, which would include a description of the packet's contents and this would be in the shipment acknowledgment and also utilized in the electronic receipt signed by the physician and transmitted back to the central server. See also, The primary features will be to ensure that we're complaint with the new federal Prescription Drug Marketing Act regulation. These regulations cover the distribution of pharmaceutical product samples. PhasTrak will let sales reps dial in to their company servers to upload account information they'entered throughout the day. The central servers will update their handheld databases so they're always working with the most current product and customer information. Gayle Ehrenman, Enterprise Handheld Applications – Cut Your Data Down to Size – The Unrelenting Need for Fresh Data – Fast – is driving the increased use of handhelds, InternetWeek, Iss. 811, May 1, 2000, pg. 49. Thus, the current product information uploaded would include the description of the packet's content's to the local inventory

lawyers: that patent examiners are abysmal communicators, both orally and in writing,"[17] the Examiner has made every effort to clarify his position regarding claim interpretation and any rejections or objections in this application. Furthermore, the Examiner has provided Applicant(s) with notice—for due process purposes—of his position regarding his factual determinations and legal conclusions. If Applicant(s) disagree with *any* factual determination or legal conclusion made by the Examiner in this Office Action whether expressly stated or implied,[18] the Examiner respectfully requests Applicant(s) *in their next response* to expressly traverse the Examiner's position and provide appropriate arguments in support thereof. Failure by Applicant(s) *in their next response* to traverse the Examiner's positions and provide appropriate arguments in support thereof will be considered an admission by Applicant(s) of the factual determinations and legal conclusion not expressly traversed.[19] By addressing these issues now, matters where the Examiner and Applicant(s) agree can be eliminated allowing the Examiner and Applicant(s) to focus on areas of disagreement (if any) with the goal towards allowance in the shortest possible time.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer I. Harle whose telephone number is 703.306.2906. The examiner can normally be reached on Monday through Thursday, 6:30 am to 5:00 pm,.

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[17] Sabra Chartrand, *A Bid to Overcome Patent Backlogs*, 152 N.Y. Times C2 (Sept. 23, 2002).

[18] E.g., if the Examiner rejected a claim under §103 with two references, although not directly stated, it is the Examiner's implied position that the references are analogous art.

[19] See also MPEP §714.02, 37 CFR §1.111(b), and 37 CFR §1.104(c)(3).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert Olszewski can be reached on 703.308.5183. The fax phone number for the organization where this application or proceeding is assigned is 703.872.9326.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703.308.1113.

Jennifer Ione Harle
November 16, 2003